IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of: Mathur, et al.

Serial No.: 09/707,121 Group Art Unit: 1652

Filed: November 6, 2000 Examiner: Y. Pak

For: NOVEL HUMAN KINASE PROTEIN AND POLYNUCLEOTIDES ENCODING THE SAME

Attorney Docket No.: LEX-0083-USA

9/a
1.9-3
11/2/01

AMENDMENTS AND RESPONSE UNDER 37 C.F.R. § 1.111

Commissioner for Patents
Washington, D.C. 20231

Sir:

The Applicants acknowledge the receipt of the Office Action mailed on July 05, 2001 (Paper No. 6), which has been carefully reviewed and studied. The Applicants respectfully submit the following amendments to the above-identified application and respectfully request reconsideration of the application in view of the following amendments and remarks. In order to facilitate the Examiner's evaluation of the application, Applicants have attempted to address the rejections in Paper No. 6 in the same order in which they were originally raised. Applicants believe that this response is filed in a timely manner and that no additional fee is due for the extension of time in connection with this response.

However, the Commissioner is authorized to charge any underpayment or credit any overpayment to Deposit Account No. 50-0892.

AMENDMENTS

A marked up version of the amended claims are attached as Exhibit A. A clean copy of all of the pending claims are attached as Exhibit B.

Please amend Claims 1-3 so that the text of the amended claims read as follows:

1. (Amended) An isolated nucleic acid molecule comprising at least 454 contiguous bases of a novel human kinase polynucleotide sequence described in SEQ ID NO: 1.

2. (Amended) An isolated nucleic acid molecule comprising a novel human kinase nucleotide sequence that:

(a) encodes the amino acid sequence shown in SEQ ID NO: 2; and

(b) hybridizes under highly stringent conditions to the nucleotide sequence of SEQ ID NO: 1 or the full complement thereof.

3. (Amended) An isolated nucleic acid molecule comprising a human nucleotide sequence encoding the amino acid sequence of SEQ ID NO: 2.

Please add new Claim 4 as follows:

4. (New) An isolated nucleic acid molecule comprising the nucleotide sequence of a novel human kinase described in SEQ ID NO: 1.

I. Status of Claims

Claims 1-3 are pending in the instant application. With this amendment Claims 1-3 are amended and new Claim 4 is added. For the PTO's convenience, a marked up version of the amended Claims are attached as Exhibit A. A clean copy of pending Claims 1-4 are attached hereto as Exhibit B. Please note that the only amendment to Claim 3 is the correction of a minor typographical error.

II. Support for the New Claims

Amendment of Claim 1 finds support throughout the specification as originally filed, with particular support for fragments being found at least at page 10, lines 28.

Amendment of Claim 2 finds support throughout the specification as originally filed, with particular support for highly stringent hybridization being found at least at page 4, lines 16-23.

Claim 3 has been amended to correct a minor typographical error.

New Claim 4 finds support throughout the specification as originally filed, with particular support being found in the original Claim 1.

As the amendments to Claims 1-3 and new Claim 4 are fully supported by the specification and claims as originally filed, they do not constitute new matter. Entry therefore is respectfully requested.

RESPONSE

III. Rejections Under 35 U.S.C. § 101

Claims 1-3 stand rejected under 35 USC section 101, as being allegedly not supported by a specific and substantial utility or a well-established utility. The Examiner's rejection is respectfully traversed. As taught in the application and as well known to those of skill in the art, kinase proteins play a critical role in, *intra alia*, signal transduction and cell activation. In fact, many oncogenes are kinases or kinase linked receptors. Kinases are also well known to the art as targets for compounds that inhibit cellular signaling and regulation. Many highly successful and highly profitable drug therapies are directed at kinases. Therapies directed at human kinases include, among others, many of those for cancer and several antiviral medications. Therefore, the identification of a new and novel human kinase has great utility.

So great in fact is the utility of human kinase proteins that U.S. Patent No. 5,817,479 was issued on a group of Human Kinase Homologs. This application discloses a series of polynucleotide fragments from human kinases, the shortest of which is 152 bp in length and the longest of which is 1851 bp in length. Issued U.S. Patents are presumed to meet the requirements of 35 U.S.C. sections 101, 102, 103 and 112, specifically, that

they have utility, are novel, non-obvious, are enabled, meet the written description requirements and particularly point out and distinctly claim the invention. The issuance of U.S. Patent 5,817,479 indicates that the patented kinase fragments have specific and substantial utility. Logic demands that if sequence fragments of human kinases that are as short as 152 bp in length have utility, then surely the same is true of novel kinase fragments that are greater than 152 bp, including the claimed kinase sequences that are 454 bp in length.

The effective date of U.S. Patent 5,817,479 is August 7, 1996. Given the amount of research effort directed at identifying and characterizing human kinases, the knowledge in the art regarding, as well as the utility of, human kinases over the last 4 years has increased rather than decreased. In light of the issuance of U.S. Patent No. 5,817,479 on fragments of human kinase proteins, Applicants respectfully submit that the present specification, which also describes fragments of a novel human kinase, describes a utility fully compliant with the provision of 35 U.S.C. section 101.

Although the above discussion is believed to be dispositive of the utility issue, the Applicants would like to further direct the Examiner's attention to page 8 of the present specification, which provides a detailed description of how the presently described sequences can be used to track the expression of the genes encoding the described proteins. In particular, the specification describes how the described sequences can be represented using a gene chip format to provide a high throughput analysis of the relevant cellular "transcriptome". Given the widespread utility of such "gene chip" methods of using *public domain* gene sequence information (as evidenced by the numerous issued U.S.

patents relating to chip technology for example, inter alia, U.S. Patent Nos. 5,700,637, 5,556,752, 5,744,305, 4,631,211, 5,445,934, 5,252,743, 4,713,326, 5,424,186, and 4,689,405), there can be little doubt that the use of the presently described *novel* sequences would have great utility in such "chip" applications.

Finally, as novel "full length" cDNAs, the described sequences provide *a unique (and hence, highly specific) resource* for mapping the relatively small proportion of corresponding region of the genome that actually encodes the described proteins. In view of the fact that public and private efforts have spent several billion dollars to obtain human genomic sequence data (and that corporate partners have committed to spending millions of dollars for early access to human genomic sequence), one can credibly assert that genomic sequence data have a demonstrated substantial and specific utility. In fact, the Applicants submit that, in view of the overwhelming evidence to the contrary (as, for example, evidenced by the tandem issues of the preeminent scientific journals "Nature" (2001, *409*:745-964) and "Science" (2001, *291*:1304) that were both dedicated to the completion of the sequencing of the Human Genome), it is illogical to argue that genomic data has no utility. Given that there can be no credible assertion that human genomic data lacks a substantial utility, it is clear that inventions that *specifically and substantially enhance* the practical utility of genomic data must necessarily have a practical utility. This is precisely the sort of practical, or "real world," utility that is provided by the present invention.

The Examiner is respectfully requested to consider that only a minor percentage of

the genome actually encodes exons that in-turn encode polypeptide sequences. The presently described cDNAs provide biologically validated empirical data (*e.g.*, showing which sequences are transcribed, spliced, and polyadenylated) that *specifically* define that portion of the corresponding genomic locus that actually encodes exon sequence. Equally significant is that the described cDNA sequences define which exons are actually spliced together to produce an active transcript (*i.e.*, such sequences are generally required to conclusively identify functional exon splice-junctions). The Applicants submit that one skilled in the art would have clearly understood that the above *substantial and specific* utilities as inherent features of the presently described sequences.

For the reasons described above, Applicants submit that the rejection of Claims 1-3 under 35 U.S.C. section 101 has been overcome and the Examiner is respectfully requested to withdraw the pending rejection of Claims 1-3 under 35 U.S.C. section 101.

IV. Rejections Under 35 U.S.C. § 112, First Paragraph

Claims 1-3 stand rejected under 35 USC section 112, first paragraph, as containing subject matter which allegedly was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected to make and/or use the invention. The Examiner alleges that because the claimed invention is not supported by either a specific asserted utility or a well established utility (for reasons set forth in the Office Action (Paper No. 6) under the section entitled Claims Rejections-35 U.S.C. § 101) one skilled in the art clearly would not know how to use the claimed invention so that it would operate as intended without undue

experimentation.

The Examiner's rejection of Claims 1-3 under 35 USC section 112, first paragraph is respectfully traversed and overcome. The Applicants respectfully submit that, given the discussion provided above regarding well established utility and issued U.S. Patent 5,817,479, one of ordinary skill in the art would have clearly understood how to use the claimed invention, fragments of a novel human kinase, without undue experimentation. Accordingly, the Examiner is respectfully requested to withdraw the pending rejection of Claims 1-3 under 35 U.S.C. section 112, first paragraph.

In addition, Claim 1 stands rejected under 35 USC section 112, first paragraph as being allegedly indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regards as the invention.

The rejection of Claim 1 under 35 U.S.C. section 112, first paragraph has been overcome by Applicants' amendment of Claim 1 to identify the function of the encoded sequences as being from a novel human kinase. Accordingly, the Examiner is also respectfully requested to withdraw the pending rejection of Claim 1 under 35 U.S.C. section 112, first paragraph.

V. Rejections Under 35 U.S.C. § 112, Second Paragraph

Claims 1-2 stand rejected under 35 USC section 112, second paragraph, as being allegedly indefinite, for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Although Applicants believe the claims as originally filed sufficiently point out and distinctly claim the invention, in order to more

rapidly progress the case to allowance, Applicant's have amended Claims 1 and 2 to identify the function of the encoded polypeptides as being that of a novel kinase. Accordingly, the Examiner is respectfully requested to withdraw the pending rejection of Claims 1-2 under 35 U.S.C. section 112, second paragraph. Applicants note for the record that these amendments to Claims 1 and 2 in no way limit the scope of the invention beyond that in the claims as originally filed.

Claim 2 also stands rejected because the exact hybridization condition is allegedly unclear because the specification contains different stringent hybridization conditions. Although Applicants believe that this claim as originally filed sufficiently points out and distinctly claims the invention, in order to more rapidly progress the case to allowance, Applicants have amended Claim 2 to specify "highly" stringent conditions. Applicants respectfully submit that this rejection has thus been overcome by Applicant's amendment of Claim 2 to specify "highly" stringent conditions. Accordingly, the Examiner is respectfully requested to withdraw the pending rejection of Claim 2 under 35 U.S.C. section 112, second paragraph.

Claim 2 also stands rejected because the phrase "complement thereof" is allegedly unclear. The use of the term "or a complement thereof" is a common and accepted practice well understood by those of ordinary skill in the art, and reflects the fact that nucleic acids are often prepared from a double-stranded templates. Many issued U.S. Patents contain claims that use of the terms " complement thereof", for example Claims 1, 2 and 3 of U.S. Patent Number 5,955,306. As described previously, such claims are presumed valid, indicating that such language is per se definite. In spite of the fact that

Applicants believe that this claim as originally filed sufficiently points out and distinctly claims the invention, in order to more rapidly progress the case to allowance, Applicants have amended Claim 2 to include the term "full" complement thereof, because the addition of this term is not viewed by Applicants as being limiting with regard to the intent of the original Claim, nor should it be assumed to be such. Accordingly, the Examiner is respectfully requested to also withdraw the pending rejection of Claim 2 under 35 U.S.C. section 112, second paragraph.

VI. Rejections Under 35 U.S.C. § 102

Claims 1-2 stand rejected under 35 U.S.C. section 102(b) as being allegedly anticipated by Hillier *et al.* (June 29, 1995), Accession No. H16878 ("Hillier *et al.*"). The Examiner's rejection of Claim 1 is overcome by amendment of Claim 1. Hillier *et al.* describes a 453 bp fragment cDNA clone derived from infant *Homo sapiens* brain tissue whose function is unknown. However, amended Claim 1 recites fragments of a novel human kinase that are greater than or equal to 454 bp in length. Accordingly, the Examiner is respectfully requested to withdraw the pending rejection of Claim 1 under 35 U.S.C. section 102.

The Examiner's rejection of Claim 2 is both respectfully traversed and overcome by the aforementioned claim amendment. In order to "encode(s) the amino acid sequence shown in SEQ ID NO:2" as recited in Claim 2, the isolated nucleic acid molecule must be larger than the 453 bp fragment described in Hillier *et al.*

With regard to the highly stringent hybridization aspect of amended Claim 2,

Applicants respectfully submit that one skilled in the relevant art would clearly understand by utilizing the highly stringent conditions provided in the specification one could differentiate the binding of a 453 bp fragment as described in Hillier *et al.* from the sequence "as described in SEQ ID NO:1 or the full complement thereof." Accordingly, the Examiner is respectfully requested to withdraw the pending rejection of Claim 2 under 35 U.S.C. section 102.

VII. CONCLUSION

In view of the foregoing amendments and remarks, the Applicants believe that the application is in good and proper condition for allowance. Early notification to that effect is earnestly solicited.

If the Examiner feels that a telephone call would expedite the consideration of the application, the Examiner is invited to call the undersigned attorney at (281) 863-3333.

Respectfully submitted,

October 5, 2001
Date

Lance K. Ishimoto Reg. No. 41,866

LEXICON GENETICS INCORPORATED
4000 Research Forest Drive
The Woodlands, TX 77381
(281) 863-3333